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10/595,608	04/05/2007	Frederik Henricus Wittkamp	0B-049910US	3431

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ST. JUDE MEDICAL, ATRIAL FIBRILLATION DIVISION
14901 DEVEAU PLACE
MINNETONKA, MN 55345-2126

EXAMINER

SCOTT, AMANDA L

ART UNIT	PAPER NUMBER
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4185

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02/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,608	Applicant(s) WITTKAMPF ET AL.	
	Examiner AMANDA SCOTT	Art Unit 4185	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/16/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 14-18 and 21-31** are rejected under 35 U.S.C. 102(b) as being anticipated by Webster, Jr. (US 6,171,275 B1).

Regarding claim 14, Webster, Jr. discloses an elongated body having an electrode disposed at a first end thereof(view figure 1;(20 *electrode*)); at least one current-carrying wire extending through said body(16), which wire(16) is electrically connected to said electrode(20); a channel(40) extending through said body and being adapted to supply a cooling fluid through said body(40 *irrigation channel*), at least one outlet opening of the channel being provided in or near said first end(view figure 5); and a temperature sensor arranged in said first end(column 7, lines 5-10), wherein said channel is thermally insulated from said electrode(column 3, lines 64-67).

Regarding claim 15, Webster, Jr. discloses at least one outlet opening is provided in said first end (view figure 5).

Regarding claim 16, Webster, Jr. discloses wherein said channel (40) has a longitudinal direction and said at least one outlet opening comprises a series of outlet openings (41 *branches*), which outlet openings are arranged such that, during use,

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cooling fluid supplied through said channel flows out through said outlet openings in an outflow direction which forms an angle with said longitudinal direction (column 4, line 65 - column 5, line 5).

Regarding claim 17, Webster, Jr. discloses wherein said angle is between 30 and 90 degrees (column 4, line 65 - column 5, line 5).

Regarding claim 18, Webster, Jr. discloses wherein the at least one outlet opening is provided with a thermally insulating inner casing (column 4, lines 15-27 *separate lumens for infusion tubes and electrode leads*).

Regarding claim 21, Webster, Jr. discloses wherein the temperature sensor is a thermocouple attached to the casing (column 7, lines 5-10).

Regarding claim 22, Webster, Jr. discloses wherein at least one said outlet opening is provided in said body adjacent said first end (view figure 5).

Regarding claim 23, Webster, Jr. discloses wherein said first end is attached to said body, and said temperature sensor is provided in said first end at a distance from an interface formed between said body and said first end (column 7, lines 6-14).

Regarding claim 24, Webster, Jr. discloses wherein at least one outlet opening is formed such that cooling fluid flowing therefrom during use flows away from said first end (view figure 5). Fluid has to flow away from the first end because of the angle of the branches.

Regarding claim 25, Webster, Jr. discloses, wherein said first end has at least one metal exterior (column 3, lines 39-41).

Regarding claim 26, Webster, Jr. discloses wherein the at least one outlet opening is arranged such that turbulence is generated around the first end when cooling fluid flows there through (view figure 5). *Turbulence is formed at the opening of the branches (41) as well as internally at the beginning of the branches from the channel).*

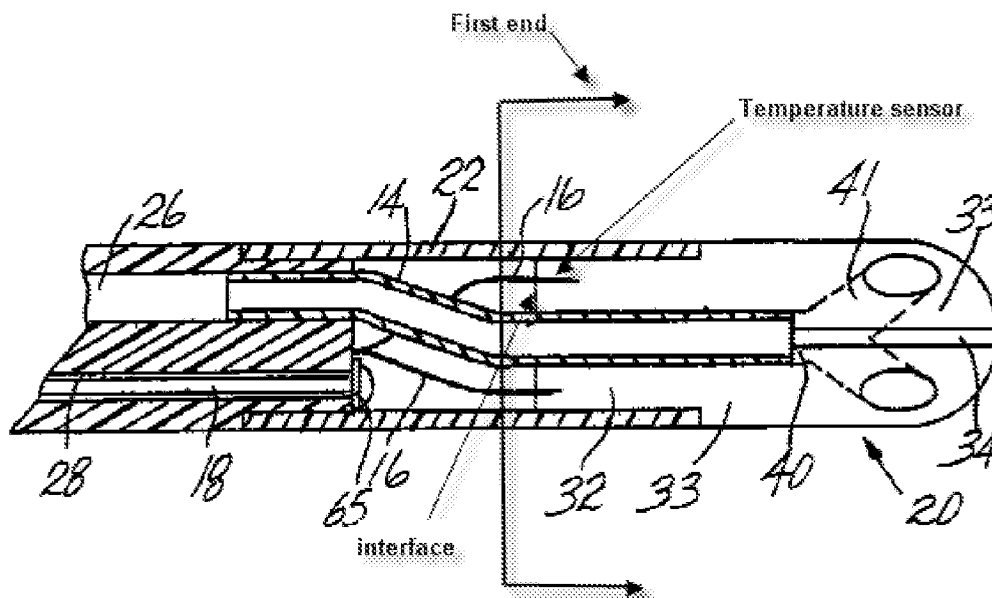
Regarding claim 27, Webster, Jr. discloses an elongated body having an outer surface and an electrode disposed at a first end thereof(view figure 1; (electrode(20)); at least one live wire extending through said elongated body(16), said at least one live wire(16 being connected to said electrode)column 3, line 65); a channel extending through said elongated body(40), said channel being adapted to deliver a cooling fluid through said elongated body(40 *central irrigation channel*); at least one thermally insulated outlet opening extending from said channel(view figure 5; 41) to said outer surface of said elongated body at or near said electrically conductive first end (33 *electrode*); and a temperature sensor arranged in said first end(column 7, lines 5-10).

Regarding claim 28, Webster, Jr. discloses wherein said channel (40) has a longitudinal axis, wherein said at least one thermally insulated outlet opening comprises a series of outlet openings adapted to deliver said cooling fluid toward said outer surface of said elongated body in an outflow direction (41), and wherein said outflow direction is at an angle relative to said longitudinal axis (column 4, lines 15-27; *separate lumens for infusion tubes and electrode wires*).

Regarding claim 29, Webster, Jr. discloses wherein said at least one thermally insulated outlet opening comprises a thermally insulating inside casing (column 4, lines 15-27; (34; *insulation*)).

Regarding claim 30, Webster, Jr. discloses at least one thermally insulated outlet opening (41) is provided in said elongated body, adjacent to said first end (view figure 5).

Regarding claim 31, Webster, Jr. discloses wherein said first end is attached to said elongated body, wherein said temperature sensor is provided in said first end at a distance from an interface formed between said elongated body and said first end (column 7, lines 5-10; view figure below).



Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. **Claims 19 and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster, Jr. (US 6,171,275 B1) in view of Rydell (US 5,098,431).

Regarding claim 19, Webster, Jr. discloses the claimed catheter, but fails to explicitly disclose wherein the first end includes: a core manufactured from a material having low thermal conductivity and/or low electrical conductivity; and a casing having a good heat conductivity and/or good electrical conductivity relative to the core. Webster

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discloses that *the catheter body can be made of any suitable construction and made of any suitable construction.*

However, Rydell discloses a core manufactured from a material having low thermal conductivity and/or low electrical conductivity; and a casing having a good heat conductivity and/or good electrical conductivity relative to the core (column 3, lines 12-20).

7. It would have been obvious to one having ordinary skill in the art at the time of invention to combine the catheter taught by Webster, Jr. with the core and casing taught by Rydell. Doing so would allow the catheter to work properly with the operating electrodes within the body.

Regarding claim 20, Webster, Jr. discloses the claimed catheter, but fails to disclose wherein the core is made of plastic, ceramic, or glass, and wherein the casing is made of metal.

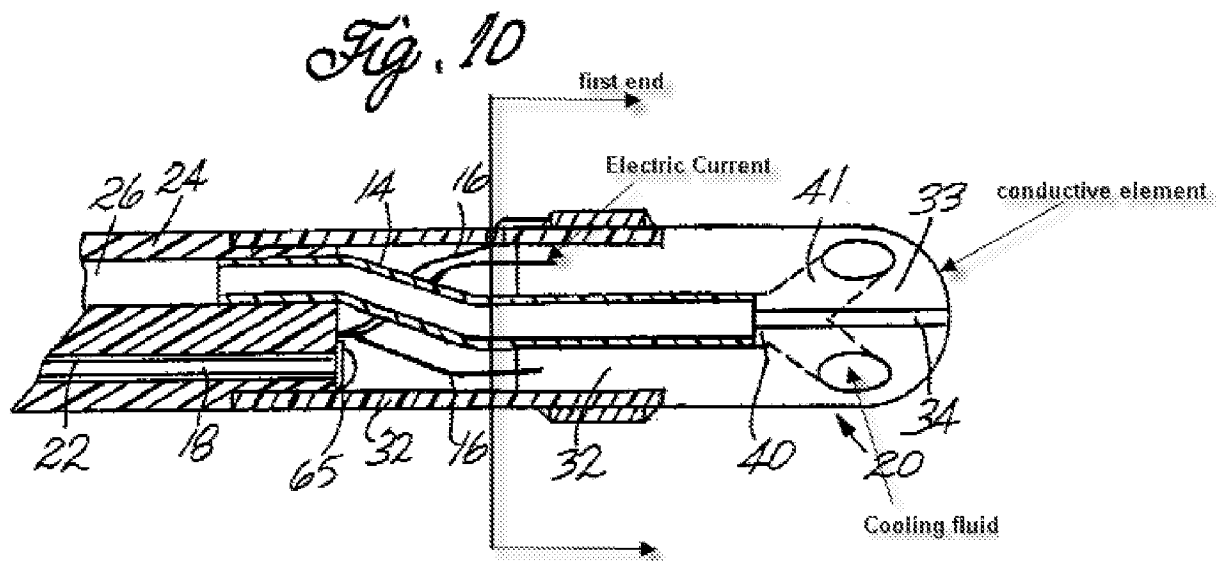
However, Rydell discloses wherein the core is made of plastic, ceramic, or glass, and wherein the casing is made of metal (column 3, lines 12-20).

8. It would have been obvious to one having ordinary skill in the art at the time of invention to combine the catheter taught by Webster, Jr. with the ceramic core and metal casing taught by Rydell. Doing so would allow the catheter to work properly with the operating electrodes within the body.

9. **Claims 32-34 and 36-37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster, Jr. (US 6,171,275 B1).

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Regarding claim 32, Webster, Jr. discloses wherein a catheter(11) having an electrode(30) disposed at a first end thereof is provided in a body cavity, with said first end near or, preferably, against a wall of said body cavity, while at a distance from said first end a complementary electrically conductive element is arranged, whereupon an electric current is generated between said first end and said conductive element, such that said wall is heated, whereupon, adjacent said first end, a cooling fluid is dispensed, while the temperature of said first end is measured and is regulated, while direct cooling of said first end from the inside thereof by said cooling fluid is prevented(view figure below). Webster, Jr. fails to explicitly disclose the claimed method.



10. It would have been obvious to one having ordinary skill in the art at the time of invention to use the apparatus taught by Webster, Jr. in the claimed method since it is

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an understandable method of use. Doing so is a way that the apparatus can be used to heat and ablate tissue.

Regarding claim 33, Webster, Jr. discloses, wherein said cooling fluid, through a channel(40) in said catheter(11), is supplied and dispensed in a protein containing liquid(abstract text, blood), while said cooling fluid in said catheter is separated from at least said first end through thermal insulation(column 4, lines 15-27; *separate lumens for infusion tubes and electrode leads*). Webster, Jr. fails to explicitly disclose the claimed method.

11. It would have been obvious to one having ordinary skill in the art at the time of invention to use the apparatus taught by Webster, Jr. in the claimed method since it is an understandable method of use. Doing so is a way that the apparatus can be used to heat and ablate tissue.

Regarding claim 34, Webster, Jr. discloses, wherein the cooling fluid is dispensed in a protein containing liquid such as blood around said first end such that said protein containing liquid is cooled with the aid of said cooling fluid adjacent an interface between said protein containing liquid and said wall and near the outside of said first end and is kept at a temperature below the coagulation temperature of said protein containing liquid (view above figure; column 10, lines 47-63). Webster, Jr. fails to explicitly disclose the claimed method.

12. It would have been obvious to one having ordinary skill in the art at the time of invention to use the apparatus taught by Webster, Jr. in the claimed method since it is

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an understandable method of use. Doing so is a way that the apparatus can be used to heat and ablate tissue.

Regarding claim 36, Webster, Jr. discloses wherein the cooling fluid comprises a physiological salt solution (column 6, lines 48-53), wherein the physiological salt solution is introduced into said protein containing liquid (abstract; blood) such that around said first end, turbulence occurs in said protein containing liquid (*Turbulence is formed at the opening of the branches (41) as well as internally at the beginning of the branches from the channel*). Webster, Jr. fails to explicitly disclose the claimed method.

13. It would have been obvious to one having ordinary skill in the art at the time of invention to use the apparatus taught by Webster, Jr. in the claimed method since it is an understandable method of use. Doing so is a way that the apparatus can be used to heat and ablate tissue.

Regarding claim 37, Webster discloses wherein the electrically conductive element is disposed outside the body in which said cavity is located (view figure 1, 20(electrode)). Webster, Jr. fails to explicitly disclose the claimed method.

14. It would have been obvious to one having ordinary skill in the art at the time of invention to use the apparatus taught by Webster, Jr. in the claimed method since it is an understandable method of use. Doing so is a way that the apparatus can be used to heat and ablate tissue.

15. **Claim 35** is rejected under 35 U.S.C. 103(a) as being unpatentable over Webster, Jr. (US 6,171,275 B1) in view of Simpson et al (US 6,049,737).

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Regarding claim 35, Webster, Jr. discloses wherein said ablation is performed in a body cavity wherein blood is present (abstract text; column 1, lines 10-39), but fails to disclose the temperature of said blood is kept at a temperature below approximately 55°C and the temperature of said first end is regulated such that it remains below approximately 65°C.

However, Simpson et al. discloses the temperature of said blood is kept at a temperature below approximately 55°C and the temperature of said first end is regulated such that it remains below approximately 65°C (column 2, lines 1-9).

16. It would have been obvious to one having ordinary skill in the art at the time of invention to combine the ablation device taught by Webster with the temperature limits set by Simpson. The method as claimed can be performed by the apparatus of Webster. It would have been obvious to use the device to perform ablation within the temperature settings because it is known in the art to keep the temperature of the electrode low as well as keeping the temperature of the tissue low so as to have the surgical procedure be effective at ablation.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. McClurken (US 7,311,708 B2).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMANDA SCOTT whose telephone number is (571)270-7103. The examiner can normally be reached on Monday thru Friday, 9:00 A.M. to 5:00 P.M..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on (571)272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AMANDA SCOTT/
Examiner, Art Unit 4185

/Terrell L McKinnon/
Supervisory Patent Examiner, Art Unit 4185